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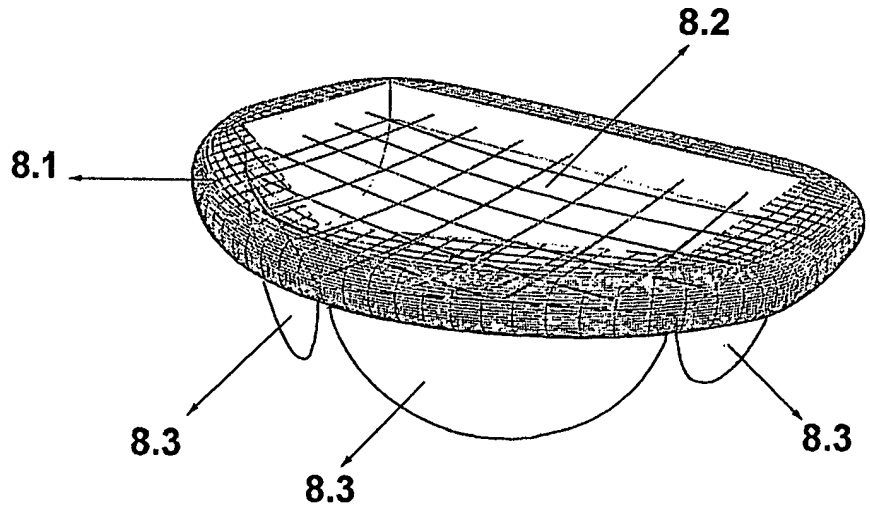
(54) Title: A MITRAL WEB APPARATUS FOR MITRAL VALVE INSUFFICIENCIES



(57) Abstract: The present invention provides an apparatus, which controls the blood flow between the left atrium (1) and left ventricle (2) and is employed in the disfunctioning of mitral valve (3) that comprises anterior and posterior leaflets (3.1, 3.2), such apparatus characterized in comprising a frame (8.1) to provide attachment to mitral annulus (3.3); a net component (8.2) covering the interior surface of said frame (8.1) to restrict the displacement of said leaflets (3.1, 3.2) towards the left atrium (1) when the left ventricle (2) is contracted so as to provide full closure; and at least one artificial leaflet (8.3) embodied on the parts of said frame (8.1) facing the posterior leaflet (3.2) opening towards the left ventricle (2) to support the function of said posterior leaflet (3.2).

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A MITRAL NETWORK APPARATUS FOR MITRAL VALVE INSUFFICIENCIES

Technical Field

The present invention relates to embodiments employed in eliminating mitral valve diseases, as one disease requiring open heart surgery operations.

Mitral valve disease is one of the most frequently encountered heart diseases. As can be seen from Figure 1, the mitral valve (3) separates the chambers of heart, namely the left atrium (1) from the left ventricle (2). Oxygenated blood that returns from the lungs into the left atrium passes through the mitral valve, which opens as the left ventricle relaxes and the left atrium contracts, and arrives at the left ventricle. This oxygenated blood is transferred to the aorta (4) with the contraction of left ventricle and thus distributed to the entire body. Meanwhile, the mitral valve closes and prevents blood from flowing backward into the left atrium. When failures emerge in the function of this valve, namely the mitral valve, both the left ventricle's efficient functioning is destroyed, and haematoma is formed in lungs with the flowing-back of blood into the left atrium. This condition makes the clinical picture called as the "mitral valve disease."

As can be seen from Figure 2, the mitral valve is anatomically composed of 4 components:

1. **Mitral annulus (3.3):** It is a fibrous structure, which surrounds the mitral valve and retains the latter to the heart

2. **Leaflets (3.1, 3.2):** There are two leaflets, one anterior leaflet (3.1) and one posterior leaflet (3.2). The anterior leaflet is relatively longer, but the site holding the annulus is relatively narrower, holding the front 1/3 part of annulus. The posterior leaflet is relatively shorter, but is broader, occupying the rear 2/3 part of annulus.

3. **Chordae tendinae (3.4):** They originate from papillary muscles and adhere to the lower parts of both leaflets (on the ventricle part). The function of these fibrous formations amounting to 25-35 in number and holding almost all parts of leaflets is to prevent the leaflets from slipping into the left atrium, as a result

of the pressure they, namely the leaflets, suffer as the left ventricle contracts.

4. **Papillary muscles (3.5):** There are two papillary muscles, one anterior and one posterior. They are attached to the left atrium wall. When the left ventricle is compacted, they contract, avoiding the leaflets from slipping back into the left atrium by means of the chordae tendinae, which are attached to the former, namely the papillary muscles.

Figure 3, illustrating a vertical cross-section of a heart is given to make clear the position of mitral valve in the heart.

Thus, an efficient functioning of the mitral valve depends on the coordinated and adequate functioning of all these four components. Failure of one of these components causes to disfunctioning. So, the causes leading to insufficiency in mitral valve can be given as following:

1. Retraction of leaflets (puckering of leaflet tissue leads to insufficient closure when two leaflets come together)

2. Annular dilatation (even when the leaflets are normal, expansion of annulus causes the leaflets to become distant from each other, leading to insufficient closure)

3. Chordae anomalies (Chordae break-off, chordae elongation, chordae shortening, and other problems occurring at chordae destroy both leaflet's mutual coaptation at the same level. The tips of leaflets cannot come together as a result of insufficient closure or excessive opening (prolapse), causing to insufficiency. Figure 4 depicts a heart with chordae elongation. As is seen, the mitral valve, which must prevent blood from flowing into the left atrium by entirely closing when the left ventricle is contracted, does not close due to chordae elongation and fail to fulfill its function.

Under the light of the foregoing, it is only possible with a surgical treatment to treat a mitral valve disorder of a certain severity. This treatment can be performed by replacing the mitral valve with one of currently available mitral valve prosthesis or by repairing the heart's mitral valve with various surgical methods.

Background of Invention

Various prosthesis are used in place of mitral valves (mitral valve replacement) in the prior art. Such prosthesis and their drawbacks shall be explained in detail as following.

1. **Mechanical valve prosthesis:** They are supplied as uni-leaflet and bi-leaflet valves. Figure 5 gives a mechanical valve prosthesis (5), showing a ring part (5.1) on the outmost periphery providing the implantation of the former (5) to the mitral valve site. This part is manufactured from a cloth-like material called Dacron allowing a convenient suturing and is attached tightly to the frame of the valve. Inside the frame, movable pieces (5.2) made of pyrolytic carbon providing the real closure function, and supporting pieces ensuring a sound attachment of the former (5.2) to the frame are accommodated. When such mechanical prostheses are employed for mitral valve replacement, a patient undergoing such replacement operation becomes obliged for lifetime to receive an anticoagulant therapy for blood dilution and coagulant prevention. There are disadvantages such as brain vessel obstructions caused by small clots, medicament-dependent bleeding, infection, valve blockage due to blood clots.

2. **Bioprosthetic valves:** These are made from tissues obtained from animals. As can be seen in Figure 6, showing an illustration of such valve, bioprosthetic valves (6) like mechanical valve prosthesis comprise a ring part (6.1) for implantation. The half-moon-like tissue pieces (6.2) attached to the frame of the valve performs the closing function. There is no need to use anticoagulant medicaments in bioprosthetic valves. Such valves, however, become impaired due to foreign tissue reactions, and must be replaced in an average of 10-year intervals.

In addition to the foregoing, there are also various embodiments and methods in the prior art to repair mitral valves without replacing it. Below will be such embodiments discussed in detail.

1. **Mitral Annuloplasty Ring:** One of the mechanisms causing to insufficiency in mitral valve is the expansion occurring at the annulus of mitral valve surrounding the latter and providing its attachment to the heart. Such

expansion separates apart the two leaflets making up the mitral valve and causes to insufficiency development. In this case, mitral annuloplasty ring implantation constricts the mitral annulus and eliminates insufficiency by restoring the position of or bringing back near to each other the leaflets. This embodiment is supplied as rigid, flexible, and semi-rigid products. Figure 7 gives an illustration of an annuloplasty ring (7).

2. **Surgical Methods:** The surgical methods employed in the prior art can be given as following: triangular resection, quadrangular resection, sliding plasty, chordae shortening, chordae transfer, chordae creation, edge-to-edge repair. One or more of such surgical methods are implemented according to the pathology at the mitral valve and are commonly combined with the aforesaid mitral annuloplasty ring.

Mitral valve repair is preferred over valve replacement, since in this case the patient's own valve is maintained, it is more physiological, and does not necessitate anticoagulant medicament. Mitral valve repair, however, is complex due to the structure of the valve and requires experience. All mitral valve repairs, except edge-to-edge repair, meaning suturing edge to edge the free end of leaflets, are directed to maintaining the physiology and working principles of normal mitral valve, like, for instance, forming a new chordae in place of a broken-off or elongated chordae tendinae, or cutting-off a prolapsed piece and rejoining the remaining pieces. Repair is particularly difficult in insufficiencies with the anterior leaflet, and even when such repairs are performed, the outcomes are unsatisfactory and soon require new surgical operations. Such outcomes are substantially dependent on the surgeon and his/her experience.

Brief Description of Invention

The present invention relates to a novel mitral net apparatus eliminating all aforesaid drawbacks and designed to be employed at the mitral valve site.

The main objective of the mitral net apparatus to be disclosed under the present invention is to undertake the roles of papillary muscles and chordae tendinae at leaflets and thus to provide the halting of leaflets at coaptation points between the left ventricle and left atrium by supplying a support from above. It is hereby put forth

a new concept for mitral valve reconstruction, and in contrast with previously employed repair methods, the novel mitral net apparatus alters the working principle of the mitral valve that was formerly dependent on such 4 components.

So the following advantages become available:

- Pathologies such as anterior leaflet prolapse and prolapse of both leaflets, which were impossible to repair or difficultly repaired with unsatisfactory outcomes, are repaired more easily, efficiently, and swiftly.

- It simplifies the mitral valve repair. It avoids the surgeon-dependent dimension of repair.

- It allows mitral valve repairs to be performed in relatively shorter time intervals, thus making it possible to reduce the interconnection period of a patient and heart-lung machinery and also the related complications.

- Thanks to the built-in membranes, it makes repairs feasible by using merely the anterior mitral valve leaflet -even when posterior mitral valve leaflets are restrictive- and by providing membrane support in other sites.

- It is manufactured very inexpensively as compared to mechanical mitral valve prostheses. Since it makes it possible the repairs of valves, which could not be repaired previously, it reduces the use of mitral valve prosthesis.

- The resection need of mitral valve is eliminated, unless it is very restrictive or calcific. Complications such as left ventricle disfunctioning and posterior rupture are avoided.

- Since it will not require anticoagulant medicament usage, complications related to the former are eliminated.

As a result, to realize the aforesaid objectives the present invention provides an apparatus, which controls the blood flow between the left atrium and left ventricle and is employed in the disfunctioning of mitral valve that comprises anterior and posterior leaflets, said apparatus characterized by comprising a frame to provide attachment to mitral annulus; a net component covering the interior surface of said

frame to restrict the displacement of said leaflets towards the left atrium so as to provide full closure when the left ventricle is contracted; and at least one artificial leaflet embodied on the parts of said frame, facing the posterior leaflet, and opening towards the left ventricle to support the function of said posterior leaflet.

In a preferred embodiment of the present invention, the exterior and interior of said frame are shaped circular and polygonal, respectively, to provide full compliance with the anatomical shape of mitral annulus.

In another preferred embodiment of the present invention, the exterior of said frame is shaped like a half-circle and the interior thereof is shaped pentagonal to comply with said half-circle form.

Yet in another preferred embodiment of the present invention, said frame is made of a rigid material, while its exterior surface is covered with a soft cloth texture.

Still in another preferred embodiment of the present invention, said net component comprises plurality of wires, which are spaced apart therebetween, extending between the interior borders of said frame by intersecting each other in a way that said net component makes a slight convexity towards the left ventricle.

In a further preferred embodiment of the present invention, the interior of said pentagonal shaped frame comprises artificial leaflets attached to four edges, none of which is the longest edge that corresponds to the mitral valve's anterior leaflet, of the mitral valve so that said artificial leaflets are passively opened towards the left ventricle.

Still in a further preferred embodiment of the present invention, said artificial leaflets are manufactured from a thin membrane and shaped similar to a half-circle or half-ellipse.

The present invention can alternatively be embodied in the form of an apparatus employable in disfunctioning of valves controlling the blood flow between any two separate parts of the body. In this case, this apparatus can comprise a frame that has a form complying with the anatomical form of the site accommodating the valves to be repaired and providing attachment to such site; a net component covering the interior surface of said frame to restrict the displacement of leaflets as

much as required; and at least one artificial leaflet embodied on top of said frame to support the functionality of said leaflets.

Brief Description of Figures

Figure 1 gives the general anatomy of a human heart and mitral valve.

Figure 2 gives the detail of a mitral valve.

Figure 3 gives a vertical cross-section of heart and the closed position of a normal mitral valve within the heart.

Figure 4 gives a vertical cross-section of heart and the disfunctioning of the mitral valve as a result of chordae tendinae elongation.

Figure 5 shows a mechanical bi-leaflet mitral valve prosthesis.

Figure 6 shows a bioprosthetic mitral valve.

Figure 7 shows a semi-rigid mitral annuloplasty ring.

Figure 8 gives a top perspective view of the subject mitral net apparatus, when the leaflets are in closed position.

Figure 9 gives a bottom perspective view of the subject mitral net apparatus, when the leaflets are in open position.

Figure 10 gives a bottom view of the subject mitral net apparatus, when the leaflets are in open position.

Figure 11 gives a bottom view of the subject mitral net apparatus, when the leaflets are in open position.

Figure 11 shows the fully closed mitral valve leaflets approaching mutually in an annular manner after the subject mitral net apparatus is implanted.

Reference Numbers

1. Left atrium	5.1 Ring part
2. Left ventricle	5.2 Movable parts
3. Mitral valve	6. Bioprosthetic valve
3.1 Anterior leaflet	6.1 Ring part
3.2 Posterior leaflet	6.2 Movable tissue pieces
3.3 Mitral annulus	7. Annuloplasty ring
3.4 Chordae tendinae	8. Mitral net apparatus
3.5 Papillary muscles	8.1 Frame
4. Aorta	8.2 Net component
5. Mechanical valve prosthesis	8.3 Artificial leaflet

Detailed Description of Invention

As it is seen from figures 8, 9, and 10; the subject mitral net apparatus is composed of three main parts.

The first part is the frame component (8.2) of the mitral net apparatus (8). This part makes it possible to implant the mitral net apparatus (8) to the mitral annulus (3.3). Complying with the anatomic form of the mitral valve annulus (3.3), its exterior is preferably shaped like a half-circle or a parabola, whereas the interior is shaped like a pentagon with preferably one edge relatively longer than the others and preferably with a short diameter/long diameter rate as "0,75." The main framework is preferably manufactured from a rigid material like steel wire, and is covered with Dacron material, which has a soft texture to accommodate the sutures while implanting it to the mitral annulus (3.3). Notwithstanding, the geometrical form, size, and structural characteristics of said frame can be altered optionally and/or depending on a treated patient in alternative embodiments of the present invention without causing losses in the functioning of the subject apparatus.

Another significant part of the subject mitral net apparatus (8) is the net component (8.2) restricting the displacement towards the left atrium of anterior and posterior leaflets of the mitral valve (3). The net component (8.2) is embodied with wires (8.2.1) (steel preferably) manufactured from a material with adequate strength so as to form a slight convexity towards the left ventricle (2). With a more elaborated description, said wires (8.2.1) extend within/between all edges of the pentagonal interior of the frame (8.1) so as to make perpendicular angles with the edges and so to constitute a net component (8.2) comprising preferably square or rectangular shaped openings or gaps. The number of steel wires employed here are of a minimum to provide full closure of mitral valve with said inter-wire openings preferably amounting to 3-5 mm. Consequently, it becomes possible to maintain a prolapsed valve texture on a common plane with this net component.

Artificial leaflets (8.3) make the third main part of the subject mitral net apparatus (8), such leaflets attached to the lower parts of the frame (8.1) of mitral net apparatus, supporting the posterior leaflet (3.2) of the mitral valve, and manufactured from thin membranes (polytetrafluoroethylene, PTFE, preferably). With a more elaborated description, the edge (i.e. the longer edge of pentagon) of the frame (8.1) to fit the mitral valve's anterior leaflet (3.1) does not include an artificial leaflet, whereas four small (2 lateral and 2 central) artificial leaflets (8.3) are embodied on other four straight edges facing the posterior leaflet (3.2).

Such artificial leaflets (8.3) are preferably shaped like half-ellipses, and since they stay relatively lower within the mitral net apparatus (8), they are passively opened downwards; and on the other hand, when they close as the left ventricle (2) is contracted, they are retained by the net component (8.2) and closed on the plane of the net component (8.2) when their edges become superimposed (see Figure 8), supporting the function of the posterior leaflet (3.2) of the mitral valve.

In brief, the subject mitral net apparatus (3) as described hereinabove supports the papillary muscles and chordae tendinae substantially in providing full closure of the mitral valve (8), and even assume their functions, ensuring the positioning of anterior and posterior leaflets (3.1, 3.2) at the same level and preventing the prolapse of such leaflets towards the left atrium (1). As can be seen from Figure 11, with implanting the subject mitral net apparatus (8) on the mitral valve (3), the

disfunctioning shown under Figure 4 is entirely eliminated and the coaptation of leaflets is easily and completely ensured even in leaflets suffering chordae tendinae elongation.

On the other hand, the frame component (8.1) of the mitral net apparatus restores an expanded and anatomically deformed mitral annulus (3.3) into the normal size and shape. Four movable small artificial leaflets (8.3) support the functions of the posterior leaflet (3.2) of mitral valve, providing reinforcement in full closure of the valve. As mentioned in the paragraph above, no artificial leaflet support is provided on the part facing the anterior leaflet (3.1) to minimize foreign material involvement and therefore the anterior leaflet (3.1) directly contacts the net component (8.2) during closing.

Furthermore, the coaptation points (mutual contacts to provide full closure) of mitral valve leaflets are somewhat below the plane of the mitral valve annulus (3.3) and accordingly, the net component (8.2) of the mitral net apparatus (8) is formed with a slight convex towards the left ventricle (2) in compliance with the anatomy of a normal mitral valve. Thanks to this formation, the subject mitral net apparatus (8) becomes capable to eliminate insufficiencies by maintaining the leaflets on levels as required in repairing the valves that have only one portion prolapsed, whereas the rest are in normal condition.

In other alternative embodiment of the present invention, the subject mitral net apparatus can be an efficient solution further in insufficiencies of the tricuspid valve having similar functioning principles. Other embodiments with similar functioning principles can also be designed for valve defects of aorta and systemic vein. Consequently, it is obvious that any embodiments comprising a net with similar functioning principles shall fall into the coverage of claims of the present application and shall lack the novelty and inventive step criteria.

The present invention cannot be restricted with the foregoing descriptions in no way. It is clear that a person skilled in the art can produce the subject novelty by using similar embodiments and/or can apply the subject embodiment in relevant fields with similar objectives. Therefore it is clear that such embodiments shall lack the novelty and particularly the inventive step criteria and be covered under the

claims of this present application.

CLAIMS

1. An apparatus, which controls the blood flow between the left atrium (1) and left ventricle (2) and is employed in the disfunctioning of mitral valve (3) that comprises anterior and posterior leaflets (3.1, 3.2), said apparatus characterized by comprising a frame (8.1) to provide attachment to mitral annulus (3.3); a net component (8.2) covering the interior of said frame (8.1) to restrict the displacement of said leaflets (3.1, 3.2) towards the left atrium (1) so as to provide full closure when the left ventricle (2) is contracted; and at least one artificial leaflet (8.3) embodied on the parts of said frame (8.1), which are facing the posterior leaflet (3.2), and opening towards the left ventricle (2) to support the function of said posterior leaflet (3.2).

2. A mitral net apparatus according to Claim 1, characterized by comprising a frame (8.2) with a circular exterior and a polygonal interior.

3. A mitral net apparatus according to Claim 2, characterized by comprising a frame (8.2) with an exterior side shaped like a half-circle and an interior side shaped pentagonal to comply with said half-circle form.

4. A mitral net apparatus according to Claim 3, characterized by comprising a frame (8.2) being manufactured from a rigid material and having an exterior surface covered with a soft cloth texture.

5. A mitral net apparatus according to Claim 1, characterized by comprising a net component (8.2) made up of a plurality of wires, which are spaced apart therebetween, extending between the interior borders of said frame (8.1) by intersecting each other in a way that said net component (8.2) makes a slight convexity towards the left ventricle (2).

6. A mitral net apparatus according to Claim 1, characterized by comprising artificial leaflets (8.3) manufactured from a thin membrane and shaped like a half circle or half ellipse.

7. A mitral net apparatus according to any of the foregoing claims, characterized in that the interior of said pentagonal shaped frame (8.1) comprises artificial

leaflets (8.3) attached to four edges, none of which is the longest edge that corresponds to the mitral valve's anterior leaflet (3.1), of the mitral valve so that said artificial leaflets (8.3) are passively opened towards the left ventricle (2).

8. An apparatus employable in disfunctioning of valves controlling the blood flow between any two separate parts of the body, characterized by comprising a frame having a form complying with the anatomical form of the site accommodating the valves to be repaired and providing attachment to said site; a net component covering the interior surface of said frame to substantially restrict the displacement of said valves; and at least one artificial leaflet embodied on top of said frame to support the functionality of said valves.

9. An apparatus according to Claim 8, characterized in that said apparatus is employable in insufficiencies of tricuspid valve, aorta valve, and systemic vein leaflets.

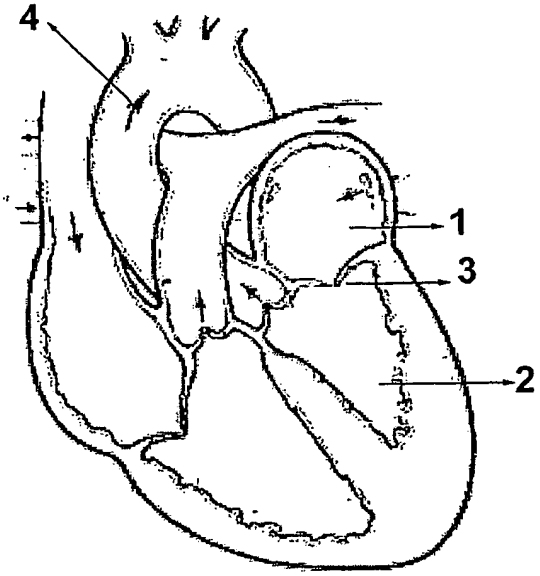

FIGURE 1

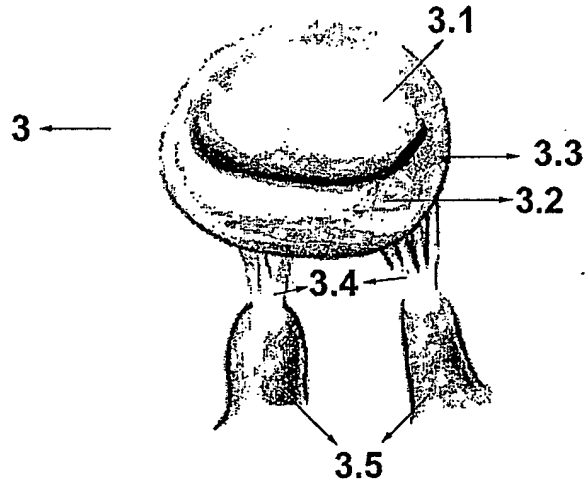

FIGURE 2

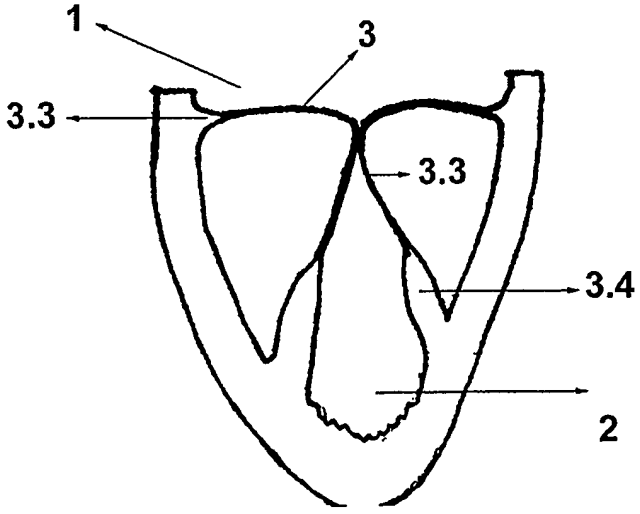

FIGURE 3

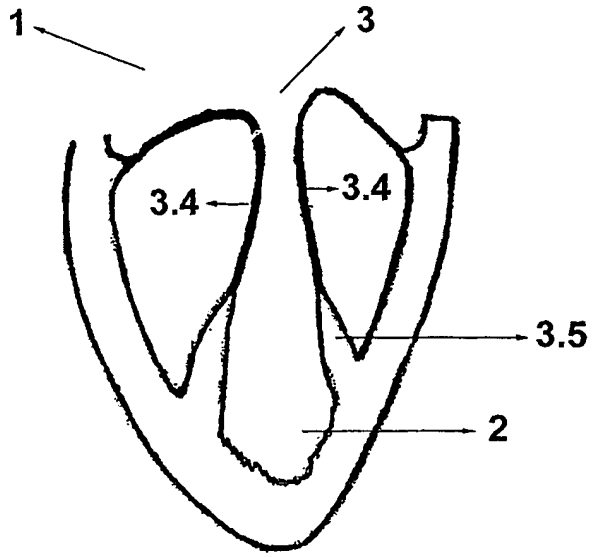

FIGURE 4

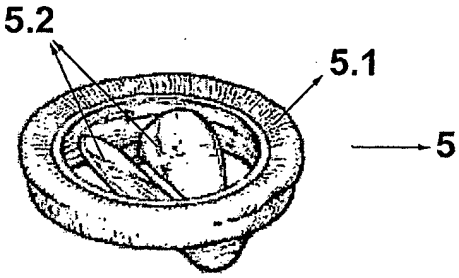

FIGURE 5

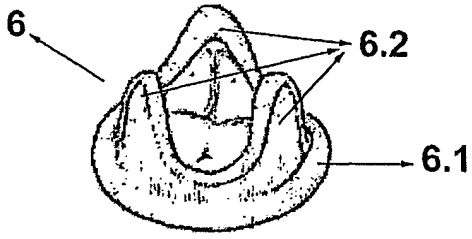

FIGURE 6

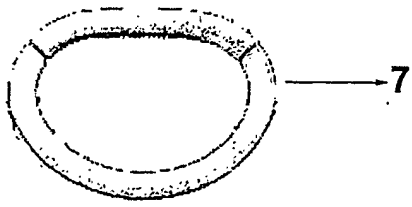

FIGURE 7

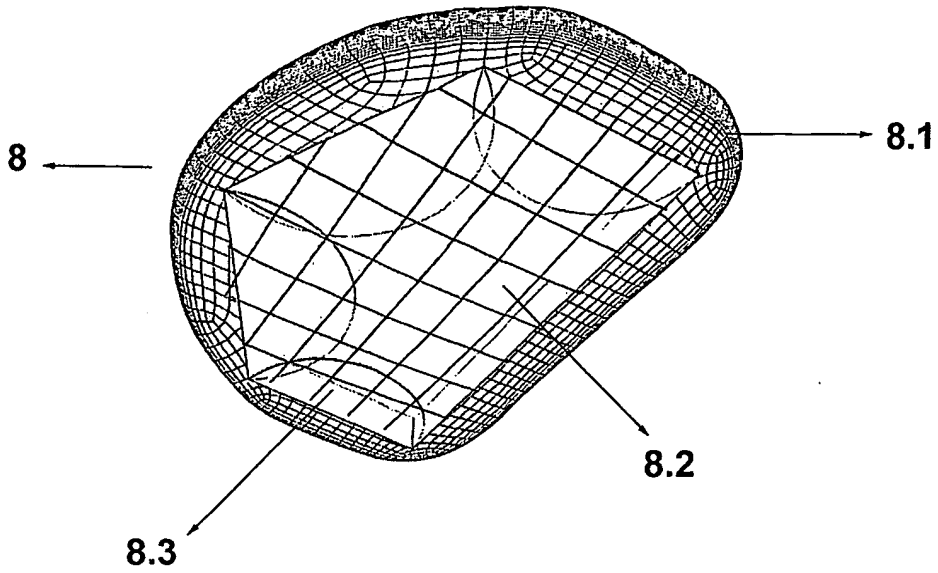

FIGURE 8

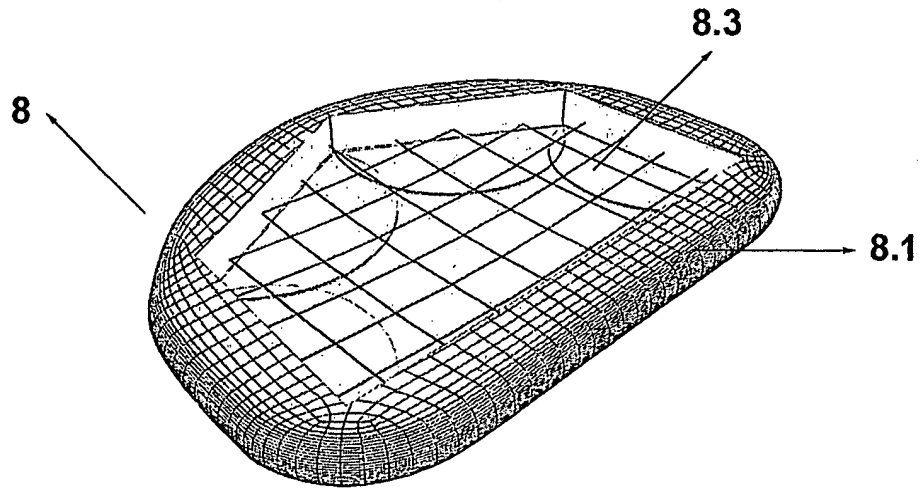

FIGURE 9

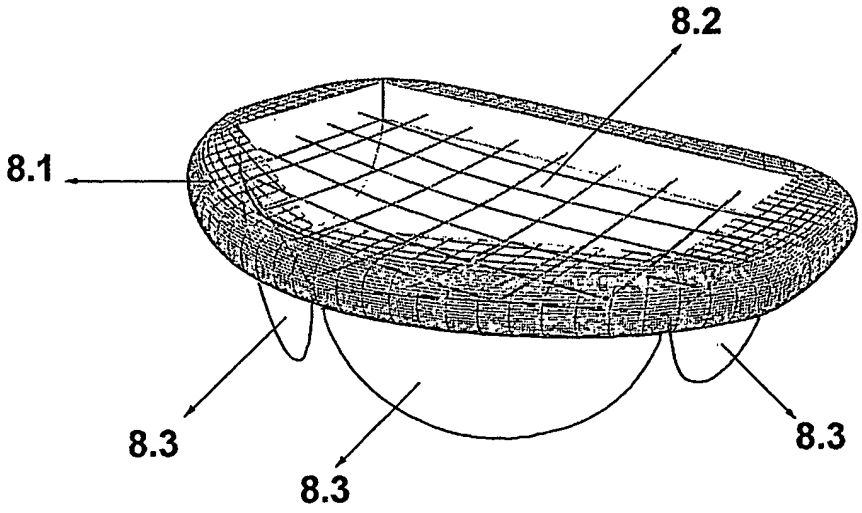

FIGURE 10

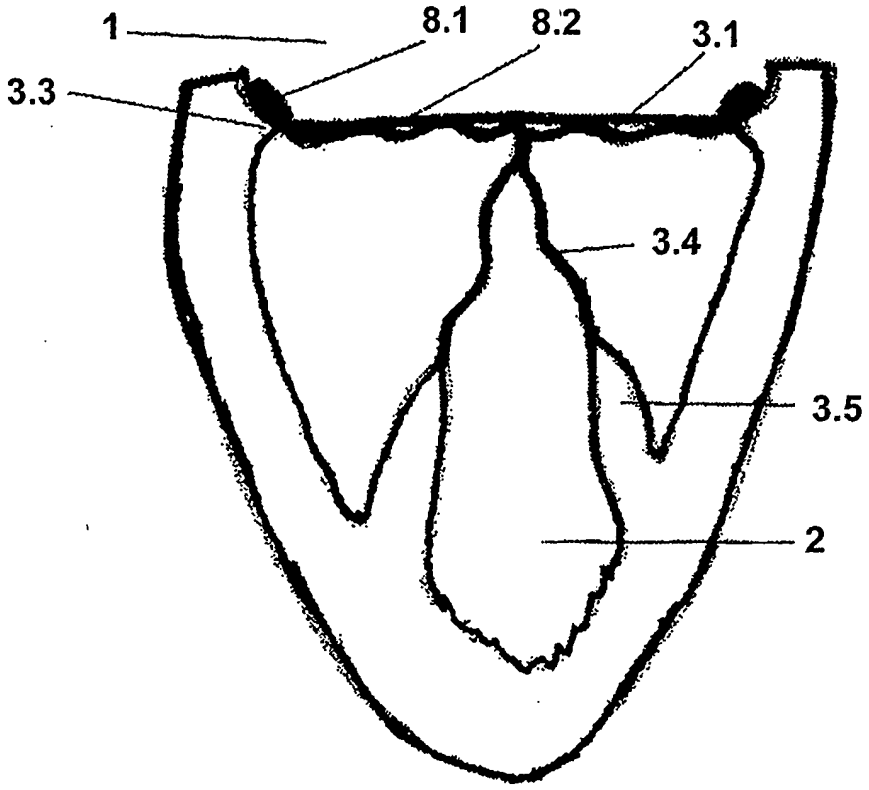

FIGURE 11

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/TR2004/000041

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/037227 A (THE UNIVERSITY COURT OF THE UNIVERSITY OF GLASGOW; WHEATLEY, DAVID, JO) 8 May 2003 (2003-05-08) figures 6-18 page 18, line 35 - page 22, line 33	1,8
A	US 6 126 590 A (ALFERNESS ET AL) 3 October 2000 (2000-10-03) figure 1 column 3, line 45 - line 67	1,8
A	US 2002/198603 A1 (BUCKBERG GERALD D ET AL) 26 December 2002 (2002-12-26) figures 11-23 paragraph '0067! - paragraph '0091!	1,8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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10 February 2005	21/02/2005

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